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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/888,313

06/22/2001

Ian Tomlinson

8039/1122

9556

29933

7590

05/26/2005

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/888,313	<b>Applicant(s)</b> TOMLINSON ET AL.	
	<b>Examiner</b> MY-CHAU T. TRAN	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 56-117 is/are pending in the application.
- 4a) Of the above claim(s) 69-77 and 87-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-68 and 78-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*20*

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/21/2005 has been entered.

### ***Application and Claims Status***

2. Applicant's amendment and response filed 09/22/2004 is acknowledged and entered. Claims 56, 78, and 86 have been amended.

3. Claims 1-55 were canceled by the amendment filed on 11/27/2002.

4. Claims 56-117 are pending.

### ***Election/Restrictions***

5. Claims 69-77, and 87-117 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to ***nonelected inventions***, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/27/2002.

6. Claims 56-68, and 78-86 are treated on the merit in this Office Action.

***Priority***

7. The formal matter issue regarding applicant claim for foreign priority under 35 U.S.C. 119 (a)-(d) has not been rectify since no certified copies of the priority documents have been received. Applicant contends in the response filed 09/22/2004 that *“Applicants filed certified copies of the two foreign priority documents on September 17, 2003, which were received and docketed by the Patent Office on September 25, 2003. A copy of the filing and the stamped return postcard are included herewith”*. However, no copy of the filing and the stamped return postcard is included in the response filed on 9/22/2004. Thus the formal matter issue regarding applicant claim for foreign priority under 35 U.S.C. 119 (a)-(d) has not been rectify.

8. Claims 56-68, and 78-86 are treated on the merit in this Office Action.


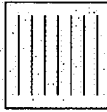
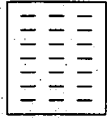

***Claim Rejections - 35 USC § 112***

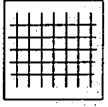
9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 56-68, and 78-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

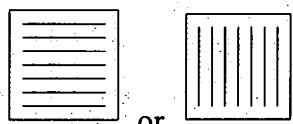
a) The phrase “series of continuous lines” is vague and indefinite because it is unclear as to the distinguishing characteristic(s) of the claimed term with regard to the claimed array such as the ‘format’. As claimed, the array would encompasses the following

formats, which are: (A)  ; (B)  ; (C)  ; (D)  ; and


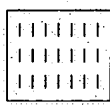
(E)  . Each of these formats would produce a different type of interaction among the polypeptides that would result in a different product. For example, in format (A) the interaction among the rows would result in polypeptides with different conformation such as tertiary structure. In format (C), the interaction among the rows, i.e. along the length of the 'lines', would result in polypeptides with different conformation such as tertiary structure. In format (C), there is also an interaction among the columns, i.e. at the end point of the 'lines', would result in the extension of the polypeptide, i.e. lengthening the polypeptide chain. In format (E), the interaction at the point of intersection as claimed in claim 65 would result in a single amino acid interaction of the polypeptide chains. Thus, the phrase "series of continuous lines" is vague and indefinite because it is unclear what constitutes the metes and bounds of "continuous lines" regarding the 'format' of the claimed array.



- b) The phrase "continuous lines" is vague and indefinite because it is unclear what constitutes the metes and bounds of the term "continuous" regarding as to its 'frame' of reference, i.e. the length of the polypeptide or a physical structure of the solid support such as a channel as claimed in claim 65. For example, if the 'frame' of reference of the term "continuous" refers to the length of the polypeptide then the type of array format and interaction produce would depend on the length of the polypeptide. The long chain polypeptide would create an array format such as

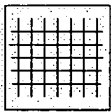
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, and the interaction among the polypeptides would result in conformation reaction such as tertiary structure. The short chain polypeptides would

create an array format such as  or , and the interaction among the polypeptides would result in conformation reaction such as tertiary structure and/or the extension of the polypeptide, i.e. lengthening the polypeptide chain. If the 'frame' of reference of the term "continuous" refers to the physical structure of the solid support such as a channel then the type of array format and interaction produce would depend on the arrangement of the channels. If the channels are arrange in rows or columns, it

would create an array format such as  or , and their would be no interaction among the polypeptides because channels structure would comprises a physical barrier between the channel of one row/column and the adjacent channel of one row/column. If the channels are arrange in rows and columns such that they

intersect, it would create an array format such as , and the interaction is at the point of intersection as claimed in claim 65 would result in a single amino acid interaction of the polypeptide chains. Thus phrase "continuous lines" is vague and indefinite because it is unclear what constitutes the metes and bounds of the term

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“continuous” regarding as to its ‘frame’ of reference, i.e. the length of the polypeptide or a physical structure of the solid support such as a channel as claimed in claim 65.

- c) The claimed method step of detection is vague and indefinite of claim 56 because it is unclear as to type of interaction being detected. For example, the polypeptides interaction between the heavy and light chain polypeptide as claimed in claim 56 would produce an interaction such as conformation interaction or the a single amino acid interaction of the polypeptide chain as claimed in claim 65. Thus, the claimed method step of detection is vague and indefinite of claim 56.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 56-68, and 78-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Wildt et al. (*Nature biochemistry*, **2000**, 18(27), pgs. 989-994) and Winkler et al. (US Patent 5,677,195).

de Wildt et al. disclose a method for screening antibody-antigen interactions, whereby many antibodies are screened in parallel against many antigens, and the filter-screening techniques is applied to the ordered arrays of antibodies generated by robotic picking and gridding (see e.g. pg. 989, right col., lines 12-16; fig. 1). The method comprise of colonies of antibodies are picked into 384 well plates and grown (see e.g. pg. 993, left col., lines 21-47; fig. 1). The colonies are then gridded in a 4x4 pattern onto a large square plate covered with a nitrocellulose filter. A second filter is coated with the ligand protein L. The first filter containing the antibodies colonies is transferred onto the plate covered with the second filter and antibody binding to the second filter is detected. The type of antibodies for the array includes scFvs (single chain fragments) such as light and heavy chain (see e.g. pg. 989, right col., lines 19-35; pg. 993, right col., line 59 thru pg. left col., line 20).

The method of de Wildt et al. differs from the presently claimed invention by failing to include an array format comprising a series of continuous lines wherein the continuous lines include continuous, non-intersecting lines or intersecting channels.

Winkler et al. disclose a method and device for forming large arrays of polymers on a substrate (see e.g. Abstract; col. 2, lines 15-55; col. 2, line 63 thru col. 3, line 10; col. 7, lines 50-55). Winkler et al. disclose to different method for forming large arrays of polymers on a substrate, which are the flow channel method and the "spotting" method (see e.g. col. 8, lines 64 thru col. 10, line 12; figs. 1, 7 (A and B), and 11A). The flow channel method comprises a)



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providing a substrate comprises a plurality of channel paths form on the x-axis of the substrate and a plurality of channel paths form on the y-axis of the substrate, b) flowing the first reagents along the plurality of channel paths form on the x-axis of the substrate for immobilization of the reagent onto the substrate, c) flowing the second reagents along the plurality of channel paths form on the y-axis of the substrate for the 'coupling' of the second reagent with the first reagent at the intersection of the two channel paths, i.e. the channel paths form on the x-axis and the channel paths form on the y-axis, d) forming the large arrays of polymers at selected regions on a substrate (see e.g. col. 8, lines 64 thru col. 10, line 12; col. 10, line 14 thru col. 11, lines 63; figs. 1, 7 (A and B), and 11A). Additionally, Winkler et al. disclose a method wherein small "strips" of reagents are applied to the substrate by stripping the substrate with a pipettor (see e.g. col. 14, lines 10-15). The substrate includes materials such polystyrene in the form of gels, pads, or sheets (see e.g. col. 10, lines 17-26; col. 14, lines 45-49). The reagents include biological material such as peptides (see e.g. col. 5, lines 32-41; col. 8, lines 8-11).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an array format comprising a series of continuous lines wherein the continuous lines include continuous, non-intersecting lines or intersecting channels as taught by Winkler et al. in the method of de Wildt et al. One of ordinary skill in the art would have been motivated to include an array format comprising a series of continuous lines wherein the continuous lines include continuous, non-intersecting lines or intersecting channels in the method of de Wildt et al. for the advantage of providing a rapid methods of preparing diverse polymer arrays with less processing step (Winkler: col. 11, lines 21-63) since both de Wildt et al. and Winkler et al. disclose the spotting method for forming an array of polymers (de Wildt: pg. 989,

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right col., lines 19-35; Winkler: col. 9, lines 59 thru col. 10, line 12). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of de Wildt et al. and Winkler et al. because Winkler et al. disclose that the striping method, i.e. forming lines on the substrate, is similar to the spotting method (Winkler: col. 14, lines 10-15). Thus the methodology of forming spots or lines on the substrate would be a choice of experimental design and is considered within the purview of the cited prior art.

***Withdrawn Rejection(s)***

14. The rejection of claims 56-66 and 78-85 under 35 USC 103(a) as being obvious over Buechler et al. (US Patent 6,057,098) in view of Miller et al. (WO 99/39210) has been withdrawn in view of applicant's amendments of claim 56.

15. The rejection of claims 56-68 and 78-86 under 35 USC 103(a) as being obvious over Buechler et al. (US Patent 6,057,098) in view of de Wildt et al. (*Nature biochemistry*, 2000, 18(27):989-994) has been withdrawn in view of applicant's amendments of claim 56.

***Response to Arguments***

16. Applicant's arguments with respect to claims 56-68 and 78-86 have been considered but are moot in view of the new ground(s) of rejection.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct  
May 25, 2005

  
PADMASHRI PONNALURI  
PRIMARY EXAMINER